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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,400	06/27/2003	Michael J. Pugia	2003P5601SUS (017191.042)	7945
28524	7590	01/26/2009	EXAMINER	
SIEMENS CORPORATION INTELLECTUAL PROPERTY DEPARTMENT 170 WOOD AVENUE SOUTH ISELIN, NJ 08830			GORDON, BRIAN R	
			ART UNIT	PAPER NUMBER
			1797	
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			01/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/608,400	Applicant(s) PUGIA ET AL.	
	Examiner Brian R. Gordon	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1-9-09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-8,33,36 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-8,33 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 9, 2009 has been entered.

Election/Restrictions

2. Newly submitted claim 39 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The previously examined invention of claim 33 does not require the broad "means" as claimed in claim 39.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 39 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

3. Applicant's arguments filed January 9, 2009 have been fully considered but they are not persuasive. Applicant's arguments mirror those of the After Final Amendments and those stated in the Interview held on 11/25/08. As previous stated in the Advisory Action of the amendment to claim 33 does not add any further structural limitations. The added phrase in (b) is directed to intended use or a process step of determining a

capillary force. Further more it is unclear what "obtains contact with said surface." In the interview applicants stated the prior art does not teach an absorbent substrate. In reviewing the previous rejection, the examiner has found that Examiner Sines addressed the limitation of the absorbent substrate via a secondary reference, Hillman.

- 5 The examiner agrees with the previous position taken by Examiner Sines. Furthermore the examiner stated to applicant that inclusion of reagent absorbent substrates within microfluidic devices is conventionally known in the art.

Applicant further amended the claim to recite the well is wider than said capillary. It is unclear what is meant by wider. Is applicant referring to the width of a sidewall,
10 bottom wall, top wall, opening, entry, etc. of the well. As pointed out in the Interview, the capillary is not positively claimed as an element of the microfluidic device. Applicant attempts to further define the well in reference to the unclaimed capillary. This is improper. Since the capillary referenced can be any capillary one chooses then the dimension (wider region) of the well will vary based on the unclaimed capillary one
15 chooses to select to use with the device.

In view of such the amendment does not further limit the scope of the microfluidic device previously claimed prior to the Final Office Action.

Applicant further discuss Applicant's problem. It should be noted that the motivation for combining references does not have to be the same motivation as that of
20 applicant nor to solve the issues that applicant identify as problems.

Applicant further argues that the recitations of the affects one desires for the posts is not intended use. The examiner disagrees. The post only have such functions

if one chooses to use the device in the same manner as applicant intends for the device to be used. If one chooses to use the device in a different manner than desired by applicant, then the structure of the posts do not change, but there that does not mean that the posts will provide for the same function as when applicant uses the device. The structure is not further limited by it's use or desired affect. If applicant intends for the device to limited to or used in a specific manner such that the desired function is achieved, applicant should consider filing an application directed to the specific method/process.

As to claim 3, asserts the configuration of Buechler is not relied upon for patentability. Reliance upon prior art for rejections is based upon the disclosure as a whole not reliance for patentability.

The arguments directed to the remaining claims were previously addressed in prior Office Actions incorporated herein.

For the reasons identified in the interview and those stated herein the previous rejections are hereby maintained.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 3, 5, 6, 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler (U.S. Pat. No. 6,113,855) in view of Hillman et al. (U.S. Pat. No. 4,756,884).

Regarding claims 5, 6, 33 and 36, Buechler teaches a microfluidic device structure comprising: an inlet port or entry 12; an enclosed capillary passageway 14 in fluid communication with the inlet port 12; an enclosed inlet chamber or well (e.g., distal region 16) having a substrate surface comprising an array of post structures (i.e., capillarity-inducing structures 30) that is also positioned adjacent the substrate; and a vent structure (i.e., escape port 18) (see col. 5, line 21 – col. 7, line 43; figures 1 & 4). As shown in figure 1, the enclosed inlet chamber 16 is in fluid communication at one side or end side thereof with the enclosed capillary passageway 14. In addition, as shown in figure 1, the vent passageway 18 is positioned at a top side of the enclosed inlet chamber opposite the entry of the capillary passageway 14 into the enclosed inlet chamber 16. The device further comprises a lid 20 that further defines a top surface of well 16 (see figure 3).

Buechler does not specifically teach a reagent deposited on an adsorbent substrate, wherein the substrate is positioned adjacent to the uniform array of posts.

The Applicant is advised that the Supreme Court recently clarified that a claim can be proved obvious merely by showing that the combination of known elements was obvious to try. In this regard, the Supreme Court explained that, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has a good reason to pursue the known options within his or her technical grasp.” An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. Indeed, the common sense of those skilled in the art demonstrates

why some combinations would have been obvious where others would not. The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. Furthermore, the simple substitution of one known element for another is likely to be obvious when predictable results are achieved. See *KSR Int'l v.*

5 *Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007) (see MPEP § 2143).

In that regard, Buechler does teach the incorporation of surface bound reagents, e.g., antibodies, on a solid phase within region 16 containing the assay volume and adjacent capillarity-inducing structures 30 (see, e.g., col. 4, lines 42 – 67; col. 5, lines
10 36 – 67; figures 1 – 4).

The use of reagent-containing absorbent substrates with similar testing devices is well known in the art. For example, Hillman et al. teaches a similar testing device that uses capillary flow and surface bound or coated reagents. Hillman also teaches that the reagents can be provided on an absorbent substrate comprising a sponge, gel,
15 membrane or filter paper within the reaction unit of the disclosed device (see, e.g., col. 15, line 66 – col. 17, line 30; in particular, col. 16, lines 55 – 61). Consequently, as shown by Hillman, a person of ordinary skill in the art would have recognized the predictable use of reagent-containing absorbent substrates with similar testing devices using capillary flow in facilitating sample fluid flow control and assaying. Therefore, it
20 would have been obvious to a person of ordinary skill in the art to substitute and incorporate a reagent-containing absorbent substrate with the disclosed microfluidic device in order to facilitate effective sample fluid flow control and subsequent testing.

Regarding claim 3, Buechler teaches the incorporation of an array of posts comprising more than one row or column of posts 30 (see figures 3, 4, 5B and 6B).

Regarding claims 5 and 6, these claim limitations would have been obvious to a person of ordinary skill in the art upon incorporation of the reagent-containing absorbent substrate with the device structure taught by Buechler. With respect to claim 5, the array of posts could be positioned above or before the absorbent substrate within well 16 so that a uniform flow of sample fluid would be established before contacting the reagent-containing absorbent substrate for analysis. With respect to claim 6, upon incorporation of the absorbent substrate, it would have been obvious to a person of ordinary skill in the art to incorporate the absorbent substrate to contact the array of posts so that a uniform distribution of sample fluid would result in contacting the reagent-containing absorbent substrate.

Regarding claim 36, upon incorporation of the absorbent substrate, it would have been obvious to a person of ordinary skill in the art that the array of posts 30 could be positioned between entry 12 and the absorbent substrate so that a uniform flow of sample fluid would contact the reagent-containing absorbent substrate.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler and Hillman et al., and further in view of Peters (U.S. Pat. No. 6,296,126).

Regarding claim 4, Buechler is silent to the specific teaching of incorporating wedge-shaped cut-out structures with the disclosed microfluidic device.

However, as shown in figure 3b, Peters does teach the incorporation of wedge-shaped cut-out structures (post or columnar projection 9 having wedge-shaped cut-outs

1) within a microfluidic apparatus for facilitating effective fluid control within a microfluidic device (see col. 1, line 10 – col. 6, line 67; figures 1a, 3b & 4).

The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007) (see MPEP § 2143).

Therefore, as evidenced by Peters, a person of ordinary skill in the art would have recognized the suitability and predictable incorporation and use of wedge-shaped cut-out structures within a microfluidic apparatus for the intended purpose of facilitating effective fluid control (see also MPEP § 2144.07). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the use of these wedge-shaped cut-out structures within the disclosed microfluidic apparatus for facilitating effective fluid control (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of wedge-shaped cut-out structures as claimed with the disclosed microfluidic device in order to provide an effective for effective sample fluid control within the microfluidic apparatus.

7. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler and Hillman, and further in view of Columbus (U.S. Pat. No. 4,233,029).

Regarding claim 7, as shown in figure 7a, Columbus further teaches the incorporation of ramp structures comprising a plateau surface structure configuration (e.g., truncated ridges 46) within a similar testing the device (see, e.g., col. 8, lines 1 – 51).

The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007) (see MPEP § 2143).

Therefore, it would have been obvious to a person of ordinary skill in the art to
5 incorporate a weir structure as claimed for facilitating effective sample fluid flow with the disclosed microfluidic device.

Regarding claim 8, Beuchler does not specifically teach the incorporation of at least one groove structure extending across the inlet chamber 16.

Columbus teaches the use of groove structures (e.g., 42 & 44) for facilitating
10 uniform fluid flow within microfluidic devices (see, e.g., col. 5, lines 1 – 55; figure 3).

The combination of familiar elements is likely to be obvious when it does no more than yield predictable results. See *KSR Int'l v. Teleflex Inc.*, 127 Sup. Ct. 1727, 1742, 82 USPQ2d 1385, 1397 (2007) (see MPEP § 2143).

Hence, as shown by Columbus, a person of ordinary skill in the art would
15 accordingly have had a reasonable expectation for success in incorporating the use of a groove structure with an analytical microfluidic device for facilitating uniform sample fluid introduction into the device for processing and analysis. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a groove structure as claimed with the disclosed microfluidic device in order to facilitate effective uniform
20 sample fluid distribution within the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, 1st Fri. Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

10 Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

15 system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian R Gordon/
Primary Examiner
Art Unit 1797